REMARKS

Claims 1-13, 15-18, 20-30, 34, 37-45 and 48-58 are pending in the present application. Claim 1 is in independent form. Claims 1, 3, 7, 9, 15-18, 34, 37, 39, 41, 45 and 48-51 are amended. Claims 52-58 are newly-added. Claims 31-33, 35 and 36 are cancelled. In view of the following remarks, favorable reconsideration and allowance of the present application is respectfully requested.

Initially, Applicants appreciate the Examiner's indication that the references submitted in the Information Disclosure Statement filed on January 25, 2007 have been considered.

I. CLAIM AMENDMENTS

By the present Amendment, claims 1, 3, 7, 9, 15-18, 34, 37, 39, 41, 45 and 48-51 are amended, and claims 52-58 are newly-added.

The amendments to claim 1 are supported, at least, by pages 9 and 10 of the Specification (PCT/DK2005/000137) and original claims 32 and 36. Claims 3, 7, 9, 15, 18, 41 and 45 have been amended to address the §112, second paragraph rejections discussed below. Claim 16, 17, 34, 37, 39 and 48-51 have been amended to provide proper claim dependency.

Newly-claims 52-56 are supported, at least, by original claims 3, 7, 9, 15 and 18, respectively. Newly-added claims 57 and 58 are supported by original claims 14 and 19, respectively.

Thus, Applicants submit that the amendments do not introduce new matter.

II. SPECIFICATION OBJECTION

The Specification stands objected to because the title of the invention is allegedly not descriptive.

In particular, the Examiner recommends amending the title to "Filtration Method for Detecting Microbial Contamination."

By the present Amendment, Applicants have amended the title as suggested by the Examiner.

Thus, Applicants respectfully request that the Examiner reconsider and withdraw the objection to the Specification.

III. CLAIM OBJECTION

Claim 18 stands objected to due to informalities. In particular, the objection states that term "methylumbelliferyl" in line 4 of claim 18 is misspelled.

As such, Applicants have amended claim 18 to reflect the correct spelling of "methylumbelliferyl." Thus, reconsideration and withdrawal of the claim objection is respectfully requested.

IV. 35 U.S.C. § 112, SECOND PARAGRAPH REJECTIONS

Claims 3, 7, 9, 15 and 18 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, the rejection states that the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. By the present Amendment, claims 3, 7, 9, 15 and 18 have been amended to remove the objectionable terminology. Furthermore, the limitations following the phrase "such as" in claims 3, 7, 9, 15 and 18 have been respectively moved into newly-added dependent claims 52-56.

Claim 35 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 35 has been cancelled.

Claim 41 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, the rejection states that "[c]laim 41 requires that the contaminants be subjected to a signal-enhancing influence. It is unclear what the metes and bounds of a 'signal-enhancing influence' would be as the term encompasses anything from temperatures, pH, chemical compounds such as polymethoxy silane, antibiotics, nutrients, etc." Action, p. 4.

By the present Amendment, claim 41 has been amended to recite "the signal-enhancing influence is one selected from the group consisting of an enzyme-enhancing substance, a selective temperature, a temperature range, a selective pH, a selective salt concentration, a non-selective growth-enhancer and a selective growth-enhancing substance." This amendment is supported, at least, by page 16, lines 6-11 of the Specification (PCT/DK2005/000137).

Claim 45 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The rejection states that the phrase "and/or" renders the claim indefinite.

Thus, Applicants have removed the objectionable terminology "and/or" from the claim.

The rejection further states that "[c]laim 45 in line 3 also requires subjecting a medium to a selective substance for yeast, fungi or bacteria. It is unclear what the metes and bounds of a 'selective substance' would be as the term encompasses anything from buffers at certain pH, antibiotics, the presence or lack of specific nutrients or nutrient combinations, etc." Action, p. 4-5.

Applicants submit that one having ordinary skill in the art of biotechnology would readily appreciate whether a substance added to an incubation medium exerts a positive selection pressure on a given type of microorganism, which is present in a mixture of microorganisms. Appreciation of this feature establishes the metes and bounds of "a selective substance," not the specific choice of selective substance used.

For the reasons given above, Applicants respectfully request that the Examiner reconsider and withdraw the §112, second paragraph rejections.

V. <u>CITED ART REJECTIONS</u>

(A) Claims 1-7, 10-13, 16, 17, 20, 22-30, 35, 36, 40-45 and 48-51 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Tuompo et al. (hereinafter "Tuompo"), U.S. Patent No. 5,714,343. Claims 1-7, 10-13, 16, 17, 20, 22-30, 35, 36, 37, 38, 40-45 and 48-51 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Tuompo in view of Koumura et al. (hereinafter "Koumura"), U.S. Patent No. 4,591,554.

i. <u>Independent Claim 1</u>

Amended independent claim 1 is directed to a method for detecting contaminants in a medium suspected of containing such contaminants including (*inter alia*) "evacuating the liquid vehicle from the influent side of the filter by forcing the liquid vehicle through to the effluent side of the filter" and "performing a quantitative or qualitative detection of the detectable moiety in the liquid vehicle evacuated in step d and correlating the detection of the moiety to the amount or presence of contaminants in the sample." Applicants submit that Tuompo and Koumura (individually, or in combination) fail to teach, or suggest, the above features recited in amended independent claim 1.

a. The Combination of Tuompo and Koumura

As discussed on page 18 of Applicants' Response filed on February 17, 2009, Tuompo teaches detection on a filter, <u>not</u> "in the liquid vehicle" as recited in amended claim 1. Further, Tuompo fails to teach, or suggest, two subsequent steps wherein the first step is evacuation of liquid vehicle from

an influent to an effluent side of a filter and the second step is detection of the detectable moiety in the evacuated liquid vehicle.

Koumura fails to cure the deficiencies of Tuompo with respect to amended independent claim 1.

Furthermore, because Tuompo recommends use of a detectable moiety which will remain on a filter surface (which is incompatible with the idea of evacuating the detectable moiety), the method taught by Tuompo would have to be extensively modified in order to incorporate the above evacuation and detection steps. Thus, Applicants submit there is no motivation to modify the method taught by Tuompo to include the evacuation and detection steps recited in claim 1, absent inappropriate hindsight of the Applicants' disclosure.

For at least these reasons, Applicants submit that Tuompo and Koumura (individually, or in combination) fail to explicitly teach, or otherwise suggest, a method for detecting contaminants in a medium suspected of containing such contaminants including "evacuating the liquid vehicle from the influent side of the filter by forcing the liquid vehicle through to the effluent side of the filter" and "performing a quantitative or qualitative detection of the detectable moiety in the liquid vehicle evacuated in step d and correlating the detection of the moiety to the amount or presence of contaminants in the sample" as recited in amended independent claim 1.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection to independent claim 1, and claims 2-7, 10-13, 16, 17, 20, 22-30, 37, 38, 40-45 and 48-51 at least by virtue of their dependency on independent claim 1.

(B) Claims 1, 3, 4, 6, 7-11, 14, 15, 17, 20-25, 27, 28, 31-36, 39 and 48-51 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Laine et al. (hereinafter "Laine"), U.S. Patent No. 6,090,573. Applicants respectfully traverse the rejection.

i. INDEPENDENT CLAIM 1

Amended independent claim 1 is directed to a method for detecting contaminants in a medium suspected of containing such contaminants including (*inter alia*) "evacuating the liquid vehicle from the influent side of the filter by forcing the liquid vehicle through to the effluent side of the filter" and "performing a quantitative or qualitative detection of the detectable moiety in the liquid vehicle evacuated in step d and correlating the detection of the moiety to the amount or presence of contaminants in the sample." Applicants submit that Laine fails to teach, or suggest, the above features recited in amended independent claim 1.

a. LAINE

Laine, directed to a method for detecting eubacteria and fungus in biological samples, discloses that a substrate is eluted by use of ethanol, but nowhere is it described that the liquid containing the substrate is forced though the filter.

Further, as discussed on pages 20-21 of Applicants' Response filed on February 17, 2009, Laine does not disclose the use of a substrate which is converted by an enzyme characteristic of the contaminants. Thus, Laine also fails to teach, or suggest, two subsequent steps wherein the first step is

evacuation of liquid vehicle from an influent to an effluent side of a filter and the second step is detection of the detectable moiety in the evacuated liquid vehicle.

Furthermore, because Laine teaches use of elution with ethanol and use of a detectable moiety which is not converted to its detectable form by being processed by enzymes characteristic of the contaminants, the method taught by Laine would have to be extensively modified in order to incorporate the above evacuation and detection steps. Thus, Applicants submit there is no motivation to modify the method taught by Laine to include the evacuation and detection steps recited in claim 1, absent inappropriate hindsight of the Applicants' disclosure.

For at least these reasons, Applicants submit that Laine fails to explicitly teach, or otherwise suggest, a method for detecting contaminants in a medium suspected of containing such contaminants including "evacuating the liquid vehicle from the influent side of the filter by forcing the liquid vehicle through to the effluent side of the filter" and "performing a quantitative or qualitative detection of the detectable moiety in the liquid vehicle evacuated in step d and correlating the detection of the moiety to the amount or presence of contaminants in the sample" as recited in amended independent claim 1.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection to independent claim 1, and claims 3, 4, 6, 7-11, 15, 17, 20-25, 27, 28, 34, 39 and 48-51 at least by virtue of their dependency on independent claim 1.

CONCLUSION

Accordingly, in view of the above, reconsideration of the objections and rejections and allowance of each of claims 1-13, 15-18, 20-30, 34, 37-45 and 48-58 in connection with the present application is earnestly solicited.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNES, DICKEY, & PIERCE, P.L.C.

Bv

John A. Castellano, Reg. No. 35,094

P.O. Box 8910

Reston, Virginia 20195

(703) 668 8000